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| EXAMINER | |
|---|---|
| HOUSTON, ELIZABETH | |
| ART UNIT | PAPER NUMBER |
| 3731 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/662,570 | STINSON ET AL. | |
| | Examiner | Art Unit | |
| | ELIZABETH HOUSTON | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *24-34 and 47-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-34 and 47-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 24-34 and 47-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (US 5,599,299) in view of Anderson (US 5,366,504

3. Weaver discloses: A stent delivery system (For example figures 17-20) comprising: (a) an inner catheter (60), said inner catheter being provided with a first longitudinally extending lumen (74); (b) perforating means (papillotome) slidably disposed in said first longitudinally extending lumen (C13:L45-46); (c) a distal tip including a plurality of distally located apertures (Fig. 20), wherein one of the plurality of apertures is in communication with the first longitudinally extending lumen and is configured to receive the perforating means (C13:L45-46); (e) a stent (62) the system further comprising an endoscope, wherein the outer catheter is sized for receipt within the endoscope and the endoscope is configured for intraoral introduction (C6:L52-58). The perforating means is a needle capable of being retracted (papillotome). The inner catheter comprises a second lumen for a guidewire (75) slidably disposed in the lumen and a guidewire (C13:L48) and a third lumen (76) for delivering a dye (C13:L49) where the lumens are in communication with the apertures. The distal tip is integral with the inner catheter and is capable of penetrating tissue without the use of a guidewire (see

Fig. 2, 6). The apertures are located approximately at the same location, face a same direction and are distal to the stent (Figs. 17-20).

4. Weaver discloses a biliary stent (62) mounted over the inner catheter but does not disclose that the stent is self-expanding with an outer catheter and the distal tip having a proximally facing surface. However Anderson discloses a biliary stent (C6:L28-31) that can be self expanding (C9:L45-48). The stent has a single component structure formed from a single material [Note that the fact that the prior art teaches additional elements does not preclude it from meeting the limitations of the claim. Also note that "single" is interpreted as *one* and not so limiting as to require one and *only one*.] The self expanding stent is made of braided filamentary material (C4:L37-38, Figs 1a, 3a); has a uniform expanded diameter (For example Fig. 1 or central portion of Fig. 2 and Fig. 5); is shaped to include a waist and a pair of cuffs (28, Fig. 2 or 76, Fig. 5). The stent is capable of draining a gastric psuedocyst. The cuffs are adapted to (capable of) engage a tissue located adjacent to the waist and disposed between the pair of cuffs to substantially limit longitudinal movement of the self-expanding stent (For example Fig. 7b, 7d shows the cuffs anchoring the stent (C9:L38-51) against tissue that is near the waist. It is understood that the anchoring will limit longitudinal movement. The waist has an expanded diameter greater than 8mm, each of said cuffs has an expanded diameter of about 15mm and the waist and the cuffs have a length of about 5-10mm(C4:L39-44). The expanded diameter is larger than a diameter of an endobiliary tube (depending on the size of the endobiliary tube). The stent is collapsible. The cuffs have an inward facing surface (for example in Figure 5) for applying a longitudinal force to the tissue

located adjacent to the waist and disposed between the inward facing surfaces of the pair of cuffs (the inwardly facing surfaces would be capable of applying a longitudinal force to tissue when placed in the claimed configuration. Further the surfaces apply frictional forces which would be longitudinal.

5. Anderson discloses the use of an outer catheter (34, Fig. 7) to surround at least a portion of the length of said inner catheter and adapted for axial movement relative to said inner catheter (C9:L45-49). The outer catheter is dimensioned to maintain said self-expandable stent in a compressed state and the stent is disposed between the inner catheter and the outer catheter. The distal tip includes a proximal facing surface having an outer diameter and the outer catheter has a distal end that disposed against the proximal facing surface of the distal tip and has an outer diameter substantially the same as the outer diameter of the distal tip (see Fig. 7).

6. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of the biliary stent of Anderson into the invention of Weaver in order to provide secure anchoring of the stent into the wall of the body lumen and prevent axial movement of the stent. It would have been obvious to incorporate the outer sheath for maintaining the stent in a compressed configuration prior to deployment. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a distal tip that has a proximally facing surface for contacting the outer sheath in order to prevent the stent from deploying prematurely.

7. Regarding claim 50, Weaver modified by Anderson does not explicitly disclose the outer catheter extends over a majority of the length of the inner catheter. However it

is old and well known for a guide catheter used as a restraining sheath in stent delivery to extend over a majority of the length of the inner catheter so that there is a proximal end that can be manipulated by the user.

8. Regarding the material of claims 27-29, it would have been obvious to one having ordinary skill in the art at the time of the invention to substitute nonabsorbable plastic or bioabsorbable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,*125 USPQ 416.

***Response to Arguments***

9. Applicant's arguments filed 12/28/09 have been fully considered but they are not persuasive. Regarding the limitation of the stent having a "single-component structure formed from a single material", although the prior art contains additional structure not required by Applicant's invention (i.e. more than one component or material), it must be noted that the prior art does disclose the invention as claimed. The fact that it discloses additional structure not claimed is irrelevant.

10. Regarding the function of the cuffs anchoring the stent, applicant argues that the prior art applies radial forces as opposed to the longitudinal force found in the instant invention. However, the since stent of Andersen has inwardly facing surfaces similar to the claimed invention (particularly Fig. 5), it would be very capable of applying longitudinal force to hold the stent in place when placed in the claimed configuration.

11. Regarding the dimensions of the stent, the claims very broadly claim that the length is "about" 15-30 mm. At the same time, the reference very broadly teaches the

dimension is "about" 40-80 mm. The reference further teaches that the lengths and diameters are variable depending on the various sized vessels into which it is inserted and the conditions of the vessel. Thus, at the very least, it would merely require routine skill in the art to vary the dimensions of the stent for these reasons.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/14/10